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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,799	11/23/2001	George Jackowski	2132.086	5599

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EXAMINER
CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
1646	8

DATE MAILED: 01/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/991,799	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Claims 1-38 are pending in the instant application.

2. Claims 1, 18, 29, 30, 33, 34 and 38 are objected to as reciting an improper Markush Group. MPEP 803.02 states that

> "Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility."

Applicant is advised that claims 1, 18, 29, 30, 33, 34 and 38 are each improper Markush claims because the plurality of amino acid sequences recited in these claims lack a common utility which is based upon a shared structural feature lacking from the prior art. Each of these amino acid sequences are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art proteins. Therefore, restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, in so far as they are drawn a biopolymer marker of SEQ ID NO: 1, classified in class 530, subclass 300, for example.

II. Claims 1-2, in so far as they are drawn a biopolymer marker of SEQ ID NO: 2, classified in class 530, subclass 300, for example.

III. Claims 1-2, in so far as they are drawn a biopolymer marker of SEQ ID NO: 3, classified in class 530, subclass 300, for example.

IV. Claims 3-9, in so far as they are drawn to a method for evidencing a disease by evidencing a biopolymer marker of SEQ ID NO: 1, classified in class 424, subclass 86, for example.

V. Claims 3-9, in so far as they are drawn to a method for evidencing a disease by evidencing a biopolymer marker of SEQ ID NO: 2, classified in class 424, subclass 86, for example.

VI. Claims 3-9, in so far as they are drawn to a method for evidencing a disease by evidencing a biopolymer marker of SEQ ID NO: 3, classified in class 424, subclass 86, for example.

VII. Claims 10-28, in so far as it is drawn to a diagnostic kit for determining the presence of the biomarker of SEQ ID NO: 1, classified in class 424, subclass 130.1, for example.

VIII. Claims 10-28, in so far as it is drawn to a diagnostic kit for determining the presence of the biomarker of SEQ ID NO: 2, classified in class 424, subclass 130.1, for example.

IX. Claims 10-28, in so far as it is drawn to a diagnostic kit for determining the presence of the biomarker of SEQ ID NO: 3, classified in class 424, subclass 130.1, for example.

X. Claims 29-32, in so far as they are drawn to an antibody that binds a biopolymer marker of SEQ ID NO: 1, classified in class 530, subclass 397.1, for example.

XI. Claims 29-32, in so far as they are drawn to an antibody that binds a biopolymer marker of SEQ ID NO: 2, classified in class 530, subclass 397.1, for example.

XII. Claims 29-32, in so far as they are drawn to an antibody that binds a biopolymer marker of SEQ ID NO: 3, classified in class 530, subclass 397.1, for example.

XIII. Claims 33-37, in so far as they are drawn to a process for identifying therapeutic avenues by using a biopolymer marker of SEQ ID NO: 1, classified in class 435, subclass 7.1, for example.

XIV. Claims 33-37, in so far as they are drawn to a process for identifying therapeutic avenues by using a biopolymer marker of SEQ ID NO: 2, classified in class 435, subclass 7.1, for example.

XV. Claims 33-37, in so far as they are drawn to a process for identifying therapeutic avenues by using a biopolymer marker of SEQ ID NO: 3, classified in class 435, subclass 7.1, for example.

XVI. Claim 38, in so far as it is drawn to a process for regulating a disease state by controlling the presence or absence of a biopolymer marker of SEQ ID NO: 1, classified in class undetermined, subclass undetermined, for example.

XVII. Claim 38, in so far as it is drawn to a process for regulating a disease state by controlling the presence or absence of a biopolymer marker of SEQ ID NO: 2, classified in class undetermined, subclass undetermined, for example.

XVIII. Claim 38, in so far as it is drawn to a process for regulating a disease state by controlling the presence or absence of a biopolymer marker of SEQ ID NO: 3, classified in class undetermined, subclass undetermined, for example.

The inventions are distinct, each from the other because of the following reasons:

3. The biopolymer markers that are inventions I to III and the antibodies that are inventions X to XII are six different chemical compositions each of which can be made and used without each other. Lack of unity is shown by the fact that these six different compositions lack a common utility based upon a shared structural feature lacking from the prior art.

4. Inventions (IV to VI), (XIII to XV) and (XVI to XVIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different methods that recite structurally and functionally distinct elements, are not required one for the other, and therefore constitute patentably distinct inventions.

5. Inventions (I to III), (VII to IX), (X to XII) and (IV to VI), (XIII to XV), (XVI to XVIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case biopolymer markers and antibodies of Groups (I to III), (VII to IX), (X to XII) could be used in an entirely different manner such as for the production of antibodies (Groups I to III) or for purification of proteins (Groups VII to XII) rather than in the methods of Groups (IV to VI), (XIII to XV), (XVI to XVIII).

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject

matter and non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. In case an invention of Groups IV to XII is elected, this application contains claims directed to the following patentably distinct species of the claimed invention: different types of body fluid or tissue samples.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 6, 16 and 23 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original

signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. OC
January 14, 2003

JOHN ULM
PRIMARY EXAMINER
GROUP 1800